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AUG 10 2007

REMARKS

Prior to the present Office Action, claims 1-23 were pending. Claims 19-23 have been canceled as being drawn to a non-elected invention. Therefore, claims 1-18 remain pending.

The Abstract has been amended as indicated above to reduce the number of words below 150.

Claims 1, 5-6, and 9-10 stand rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,736,845 to Marquez, et al. who disclose a stent assembly described, in pertinent part, as follows:

> The final component of the stent assembly 46 is an attachment means 90 for joining each of a cloth-covered stent members 74. Preferably, the attachment means 90 comprises threads or sutures sewn through the central holes in each of the circular tips 80, as shown in FIG. 5, although other suitable attachment means could be used, such as rings, cinches, or the like. The attachment means 90 may be wrapped around or sewn through the cloth cover 72. In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, as will be described below. When the stent members 74 are attached, as seen in FIG. 5, the stent 70 exhibits three cusps corresponding to the cusp region 76 of each member, and three upstanding commissures defined by the juxtaposition of adjacent pairs of commissure regions 78.
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> ...
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> In a preferred embodiment of the present invention the attachment means 90 comprises a non-bioresorbable material to ensure that the individual stent members 74 are maintained in the shape of the stent 70. In an alternative configuration, however, the attachment means 90 comprises a bioresorbable material that dissolves over a period of time after implantation.... As a consequence, each individual stent member 74 and associated leaflet 72 moves entirely independently of the others, albeit all oscillating with the natural contractions and expansions of the surrounding aortic wall. Such independent leaflet movement may greatly reduce any potential pressure drop across the valve.

Applicants first note that the Assignee and primary inventor of the present application are also the Assignee and primary inventor of Marquez, et al., and thus are fully aware of the disclosure therein. The presently claimed support frame (stent) with commissures designed to fracture upon repeated relative movement of the cusps after implantation is not present in Marquez, et al., nor in the prior art at large.

Marquez, et al. discloses flexible commissures that permit the cusps to pivot with respect to one another. In one embodiment, the commissures may be bioresorbable so as to dissolve over a period of time after implantation and permit each individual stent member 74 and associated leaflet 72 to move entirely independently of the others. The specific embodiment cited by the Examiner shows sutures 90 which connect the separate stent members 74 and may or may not be bioresorbable. Note the passage above which states that "In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, ..." That is, the sutures permit significant relative cusp movement even prior to implant and dissolution.

Claim 1 has been amended to specify that the support frame exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. Support for this change is found in paragraph [0032] of the specification. Various alternative constructions of the support member with commissures designed to fracture upon repeated relative movement of the cusps after implantation are disclosed, and each desirably exhibits a certain stiffness prior to implant to facilitate the implant procedure. That is, the surgeon typically desires a valve structure that retains its shape to simplify the delicate task of positioning the valve and/or precisely threading sutures or the like through the sewing ring. The valve of Marquez, et al., by virtue of the loose attachment means 90, features relatively movable cusps which complicate the implant process. Indeed, Figs. 23-27 of Marquez, et al. address this issue by providing a special holder that retains the shape of the valve during implant. Claim 1 has been amended to emphasize this distinction, and is believed allowable over Marquez, et al.

Claims 2-4, 8, and 11-18 stand rejected under 35 U.S.C. §103(a), as being obvious over Marquez, et al. in view of U.S. Patent No. 4,470,157 to Love, et al., the latter of which discloses various embodiments of prosthetic heart valves that can be assembled using a prefabricated kit. The valves comprise two stents that clamp tissue leaflets therebetween. The version cited by the Examiner in Fig. 16 shows a second (cap) stent made of three rods 32 welded together at their

peaks (commissures) using short sections 32d, characterized by the Examiner as being "weak notched out sections." Applicants find no basis for such an interpretation. There is no discussion of what material or weld is used for the sections 32d, and elsewhere in the patent Love, et al. specifically exclude a design that fractures:

> There is a requirement to secure the various parts of the structure together so that the valve will not become disassembled in the patient before tissue grows over it, or at any time thereafter. (Col. 4, lines 3-6)

Therefore, the sections 32d in Love, et al. are not "weak," implying they will fracture upon repeated relative movement of the cusps after implantation. Rather, the notches appear to be provided to spacially accommodate the commissures of the first stent section/leaflet assembly that is shown at the bottom of Fig. 16.

Accordingly, Applicants assert that claims 2-4, 8, and 11-18 are allowable over the combination of Marquez, et al. and Love, et al.

Based on the above amendments and remarks, Applicants believe that claims 1-18 are in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

Respectfully submitted,

Date: August 10, 2007

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